

REMARKS

Claims 1-8, 17-18 and 28-48 were pending in the present application and claims 17-18 and 38-48 have been withdrawn from consideration. Claims 1-8 and 28-37 are presently being examined. By the present amendment, which is made without acquiescence in any rejection and without prejudice to the prosecution of any removed subject matter in a related continuation, continuation-in-part or divisional application, claims 1, 2, 28 and 35 are amended to more particularly point out and distinctly claim certain embodiments of applicants' invention, and claims 6 and 38-48 are canceled. Support for the present amendment may be found in the specification, for instance, at paragraphs [0079]-[0081], [0084], and [0097]-[0105] of the published application, and elsewhere. No new matter is introduced by way of the present amendment.

REJECTIONS UNDER 35 U.S.C. § 112

The PTO rejects claim 6 under 35 U.S.C. §112, first paragraph, for alleged failure to comply with the written description requirement. In particular, the Examiner asserts that the recitation "non-circularly permuted" lacks support in the specification, and that inclusion of this term in the claim constitutes an impermissible addition of new subject matter to the application, beyond that which was originally disclosed.

Applicants respectfully traverse the rejection and submit that by the amendment submitted herewith it has been obviated by the cancellation of claim 6, solely for purposes of advancing the prosecution of the present application, without acquiescence in any rejection and without prejudice, as also noted above. The rejection is therefore moot and its withdrawal is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102

A. The PTO rejects claims 1, 5, 28 and 36 under 35 U.S.C. §102(b) for alleged lack of novelty over Chen et al. (June 2000 *J. Biol. Chem.* 275:17510). More specifically, the Examiner asserts that Chen et al. teach a pRNA multimer in which constituent

pRNAs contain other than wild-type nucleotides, thereby fitting the definition of “heterologous component” according to the instant application.

Applicants respectfully traverse these grounds for rejection. In view of the amendment submitted herewith, the instant embodiments are directed in pertinent part to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, each said chimeric pRNA monomer independently comprising a heterologous component that comprises a biologically active RNA.

It is axiomatic that for the PTO to establish a *prima facie* case of anticipation, each and every element recited by the claim must be disclosed in a single reference. See M.P.E.P. §2131. To be anticipating, the single document must disclose that the elements of the claim are combined in the same way as in the combination recited by the claim. *NetMoney IN vs. VeriSign, Inc.*, 88 USPQ2d 1751 (Fed. Cir. 2008). The instant embodiments relate to a heterologous component that comprises a *biologically active RNA*, as disclosed in the published application at, *e.g.*, paragraphs [0080]-[0082]. Where no teaching of the recited heterologous component that comprises a biologically active RNA can be found in Chen et al., it is submitted that no case of anticipation has been established such that the rejections over Chen et al. should be withdrawn.

B. The PTO rejects claims 1-6, 28-32 and 35-37 under 35 U.S.C. §102(a) for alleged lack of novelty over Hoeprich et al. (August 2003 *Gene Therapy* 10:1258). In particular, the Examiner asserts that Hoeprich et al. teach the recited combination of features, namely, a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers that each independently comprise a heterologous component (which may be siRNA or a ribozyme), wherein at least one pRNA chimera comprises an end-labeling agent.

Applicants respectfully traverse these grounds for rejection. In view of the amendment submitted herewith, the instant embodiments are directed in pertinent part to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, each said chimeric pRNA monomer independently comprising a heterologous component that comprises a biologically active RNA. As a first matter, the rejection of claim 6 is rendered moot by the cancellation of claim 6 according to the amendment submitted herewith. Hence, the rejection of

claim 6 should be withdrawn.

Applicants respectfully submit that the publication of Hoeprich et al. is not available as prior art in the present application. The PTO therefore fails to establish a *prima facie* case of anticipation under §102(a) because the presently claimed invention was not “known or used by others in this country, or patented or described in a printed publication . . . *before* the invention thereof by the applicant for a patent.” (§102(a), emphasis added). Specifically, the present application claims priority to, *inter alia*, U.S.A.N. 60/433,697, filed on December 16, 2002. (It is noted that the present application also claims the benefit, as a continuation-in-part, of U.S.A.N. 10/373,612 (February 24, 2003), which is a CIP of PCT/US01/26333 (August 23, 2001), which claims the benefit of U.S.A.N. 60/277,393 (August 23, 2000).)

Hoeprich et al. published in August 2003. Looking to the U.S. provisional application, U.S.A.N. 60/433,697, filed on December 16, 2002, from which the present application claims benefit, it is submitted that at least as early as December 16, 2002, the applicants had invented the subject matter encompassed by the instant claims. The publication of Hoeprich et al. therefore did not appear “before the invention” by the applicants of the presently claimed invention embodiments.

At pages 10-12 of the specification of priority document U.S.A.N. 60/433,697 (filed on December 16, 2002), in the final paragraph at page 26 therein, and in Figure 7 of U.S.A.N. 60/433,697, applicants disclose a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers that each independently comprise a heterologous component, which may be a biologically active RNA. It is therefore respectfully submitted that Hoeprich et al. (August 2003) cannot be properly cited as a reference by the PTO. Reconsideration is therefore requested in view of the disclosure of the priority document U.S.A.N. 60/433,697 (filed December 16, 2002). Moreover, where independent claims 1 and 28 are free of the art in view of the unavailability of Hoeprich et al. to the PTO, it is submitted that the instant claims that depend therefrom (*e.g.*, claims 2-5, 29-32 and 35-37) must also necessarily be free of the art.

It is therefore submitted that the instant claims (1-5, 28-32 and 35-37) fully satisfy the requirements of 35 U.S.C. §102. Reconsideration and withdrawal of the rejections are therefore respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103

The PTO rejects claims 1-8 and 28-37 under 35 U.S.C. §103 for alleged obviousness over Hoeprich (August 2003 *Gene Therapy* 10:1258) and Bennett et al. (U.S. Pat. No. 5,998,148). As noted above, the PTO asserts that Hoeprich et al. teach a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers that each independently comprise a heterologous component, wherein at least one pRNA chimera comprises an end-labeling agent. The PTO concedes, however, that Hoeprich et al. do not teach that at least one pRNA incorporates a nucleotide analog. Bennett et al. is alleged to remedy the deficiencies of Hoeprich et al. by teaching modified nucleotides such as 2'F modifications. The Examiner asserts that the person having ordinary skill in the art would reasonably have expected to modify the pRNA of Hoeprich et al. using the nucleotide analogues of Bennett et al.

Applicants respectfully traverse these grounds for rejection. In view of the amendment submitted herewith, the instant embodiments are directed in pertinent part to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, each said chimeric pRNA monomer independently comprising a heterologous component that comprises a biologically active RNA. As a first matter, the rejection of claim 6 is rendered moot by the cancellation of claim 6 according to the amendment submitted herewith. Hence, the rejection of claim 6 should be withdrawn.

For reasons given above in response to the rejections under §102, it is submitted that the PTO may not properly cite Hoeprich et al. (2003) under §103, where this later-published reference is not available as prior art in view of applicants' priority claim to, *inter alia*, U.S.A.N. 60/433,697, filed on December 16, 2002. As such, Hoeprich et al. must be withdrawn as a reference. Bennett et al. are asserted by the PTO merely to teach nucleic acid molecules comprising modified nucleotides such as 2'F modifications. Applicants respectfully submit that the teachings of Bennett et al. taken alone merely pertain to chemically modified nucleotides but fail to teach or in any way suggest anything having to do with pRNA, much less with a chimeric pRNA, and Bennett et al. certainly fail to teach or suggest a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, each said chimeric pRNA monomer independently comprising a heterologous component that comprises a biologically active RNA.

Accordingly, where Hoeprich et al. are not available as prior art, for reasons given above, the PTO fails to establish a *prima facie* case of obviousness under 35 U.S.C. §103. Reconsideration and withdrawal of the present rejections are therefore respectfully requested.

REQUEST FOR REJOINDER

Applicants understand that if claims directed to a product are elected for examination and found to be allowable, then withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim may later be rejoined to the application, under 37 C.F.R. §1.142. Rejoinder of previously withdrawn claims 17 and 18 is therefore respectfully requested. Applicants note that these claims directly or indirectly recite the subject matter of claim 1, which in view of the present amendment and for reasons given herein is now believed to be in allowable form.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,
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